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Oral dosage tablet for sustained release of fluvastatin, comprises hydroxypropyl methyl cellulose polymer and other excipients that are color stable upon prolonged periods of storage

Patent Assignee: NOVARTIS AG (NOVS); NOVARTIS-ERFINDUNGEN VERW GES MBH (NOVS)

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Number of Countries: 096 Number of Patents: 010

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 6242003	B1	20010605	US 2000549222	A	20000413	200150 B
WO 200178680	A2	20011025	WO 2001EP4204	A	20010411	200166
AU 200162196	A	20011030	AU 200162196	A	20010411	200219
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BR 200109943	A	20030527	BR 20019943	A	20010411	200344
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KR 2003019332	A	20030306	KR 2002712592	A	20020924	200345
CN 1422151	A	20030604	CN 2001807914	A	20010411	200356

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Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW

Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZW

AU 200162196 A A61K-009/00 Based on patent WO 200178680

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CZ 200203379 A3 A61K-009/16 Based on patent WO 200178680

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Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI TR

SK 200201462 A3 A61K-009/00 Based on patent WO 200178680

BR 200109943 A A61K-009/00 Based on patent WO 200178680

KR 2003019332 A A61K-031/404

CN 1422151 A A61K-009/20

Abstract (Basic): US 6242003 B1

NOVELTY - A color-stable sustained release tablet containing granules with a mean particle size of less than 200 microns and comprising fluvastatin and a hydroxypropyl methyl cellulose polymer (HPMC) comprising up to 12 % hydroxypropyl functionality, having a

number average molecular weight of 20000-170000 and being present in an amount of 15-50 wt.% based on the total weight of the composition, is new.

DETAILED DESCRIPTION - An INDEPENDENT CLAIM is also included for preparing a color stable sustained release oral dosage pharmaceutical composition comprising fluvastatin and a hydroxypropyl methyl cellulose polymer, by storing the composition at a relative humidity of no greater than 75 % and a temperature of 25 degrees Centigrade, the method preventing or reducing the formation of gel in the polymer.

ACTIVITY - Anticholesterol. No biological data is given.

MECHANISM OF ACTION - High mobility group (HMG) CoA reductase inhibitor.

USE - The tablets are used for the sustained release of fluvastatin and for reducing blood cholesterol levels in patients.

ADVANTAGE - The compositions of the invention are color-stable upon prolonged periods of storage and they are designed to overcome the discoloration associated with the formation of hydroxypropyl methyl cellulose polymer gel-like domains which lead to an unsightly, uneven mottled appearance.

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Derwent Class: A96; B07

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